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INFORMATION DISCOSURE STATEMEN Examining Group 1614

Patent Application
Docket No. BPD-103
Serial No. 10/071,509

February 27, 2003 David Saliwanshik

David R. Saliwanchik, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

unknown

Art Unit

1614

Applicant(s)

Alfred Fahr, Rolf Muller

Serial No.

10/071,509

Filed

February 8, 2002

Conf. No.

3436

For

Invasomes for Therapy of Disorders, their Production and Use

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed.

Please note that we are in the process of obtaining a translation of German Patent No. 199 40 227 and will furnish a copy of this document to the PTO as soon as possible.

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO/SB/08 with initials or other appropriate marks.

T:\2Linda\BPD-103-IDS-Basic-Ltr.doc/DNB/dkt

Applicants respectfully assert that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

David R. Saliwanchik

Patent Attorney

Registration No. 31,794

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2421 N.W. 41st Street, Suite A-1

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DRS/dkt

Attachments: Form PTO/SB/08 (4 pages)

Copies of cited references



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Substitute for form 1449A/PTO					Complete if Kn wn		
					Application Number	10/071,509	
INFORMATION DISCLOSURE					Filing Date	February 8, 2002	
SIA	STATEMENT BY APPLICANT				First Named Inventor	Alfred Fahr	
	(use as	many sheel	ts as necessa	ary)	Art Unit	1614	
					Examiner Name	unknown	
Shee		1	of	4	Attorney Docket Number	BPD-103	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	U1	US-5,993,851	11/30/1999	Foldvari		
	U2	US-				
	U3	US-				
	U4	US-	<u> </u>			
	U5	US-	<u> </u>	,		
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	U15	US-	<u> </u>			
	U16	US-				
	U17	US-				
	U18 U19	US-	 			
	U20	US-				

FOREIGN PATENT DOCUMENTS						
		Foreign Patent Document			Pages, Columns, Lines,	Ĭ
Examiner Initials*	Cite No. 1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
	F1	WO 92/03122 A1 (Abstract)	03/05/1992	Cevc		i –
	F2	WO 99/40932 A1	08/19/1999	Modi		
	F3	WO 01/13887 A2 (Abstract)	03/01/2001	Merckle GmbH		
	F4	DE 199 40 227 A1	03/08/2001	Merckle GmbH		
·	F5	GB 2 326 337 A	12/23/1998	Phares Pharmeceutical Research NV		
	F6					
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	F10					1

Examiner	Date	•
Signature	Considered	

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of

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Complete II Known				
Application Number	10/071,509			
Filing Date	February 8, 2002			
First Named Inventor	Alfred Fahr			
Group Art Unit	1614			
Examiner Name	unknown			
Attorney Docket Number	BPD-103			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R1 .	ABRAMS, J. R., et al., "CTLA4lg-mediated blockade of T-cell costimulation in patients with psoriasis vulgaris," Journal of Clinical Investigation, May 1999, pp. 1243-1252, Vol. 103, No. 9.	<u> </u>
	R2	AGRAWAL, S. and ZHAO, Q., "Antisense therapeutics," Current Opinion in Chemical Biology, August 1998, pp. 519-528, Vol. 2, No. 4.	
	R3	BAADSGAARD, O., "Alopecia areata: an immunologic disease?" <i>Journal of Investigative Dermatology</i> , May 1991, pp. 89S-90S, Vol. 96, No. 5.	
	R4	BLACK, K.S., et al., "Site-specific suppression of cell-mediated immunity by cyclosporine," Journal of Investigative Dermatology, May 1990, pp. 644-648, Vol. 94, No. 5.	
	R5	COLLAZO, C., and GALÁN, J., "The invasion-associated type-III protein secretion system in Salmonella – a review", Gene (1997), 192:51-59; Elsevier Science B.V.	
	R6	CARTHEW, R. W., "Gene silencing by double-stranded RNA," Current Opinion in Cell Biology, April 2001, pp. 244-248, Vol. 13, No. 2.	
	R7	CASEY, B. P. and GLAZER, P. M., "Gene targeting via triple-helix formation," <i>Progress in Nucleic Acid Research and Molecular Biology</i> , 2001, pp. 163-192, Vol. 67.	
	R8	CEVC, G., et al., Advanced Drug Delivery Reviews, 1996, pp. 349-378, Vol. 18.	
	R9	DE BOER, M. L., et al., "Role of nuclear factor of activated T cells (NFAT) in the expression of interleukin-5 and other cytokines involved in the regulation of hemopoetic cells," <i>International Journal of Biochemistry & Cell Biology</i> , 1999, pp. 1221-1236, Vol. 31, No. 10.	
	R10	ECONOMIDOU, J., et al., "Effects of cyclosporin A on immune activation markers in patients with active psoriasis," <i>Dermatology</i> , 1999, pp. 144-148, Vol. 199, No. 2.	
	R11	ELBASHIR, S. M., et al., "Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells," Nature, May 24, 2001, pp. 494-498, Vol. 411, No. 6836.	
	R12	ELLMEIER, W., et al., "The regulation of CD4 and CD8 coreceptor gene expression during T cell development," Annual Review of Immunology, 1999, pp. 523-554, Vol. 17.	
	R13	FERRANDO, J. and GRIMALT, R., "Partial response of severe alopecia areata to cyclosporine A," <i>Dermatology</i> , 1999, pp. 67-69, Vol. 199, No. 1.	

Examiner	Date	•
Signature	 Considered	<u> </u>

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

Application Number	10/071,509
Filing Date	February 8, 2002
First Named Inventor	Alfred Fahr
Group Art Unit	1614
Examiner Name	unknown
Attorney Docket Number	BPD-103

Complete if Known

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R14	GILHAR, A., et al., "Topical cyclosporin A in alopecia areata," Acta dermato-venereologica, 1989, pp. 252-253, Vol. 69, No. 3.	:
	R15	GOLLNICK and ORFANOS, C. F. Orfanos, and R. Happle, eds., <i>Hair and Hair Diseases</i> , 1990, pp. 529-569, Springer-Verlag, Berlin.	
	R16	GOSSEN, M., et al., "Inducible gene expression systems for higher eukaryotic cells," Current Opinion in Biotechnology, October 1994, pp. 516-520, Vol. 5, No. 5.	
•	R17	GRIFFITHS, C. E., et al., "Topical cyclosporin and psoriasis," Lancet, April 4, 1987, p. 806, Vol 1, No. 8536.	
	R18	GUO, J., et al., "Lecithin vesicular carriers for transdermal delivery of cyclosporin A," International Journal of Pharmaceutics, January 25, 2000, pp. 201-207, Vol. 194, No. 2.	
	R19	HAMM, H., et al., "HLA-DR and HLA-DQ antigen expression of anagen and telogen hair bulbs in long-standing alopecia areata," Archives for Dermatological Research, 1988, pp. 179-181, Vol. 280, No. 3.	
	R20	HERMANN, R., et al., "Topical Ciclosporin for Psoriasis: In vitro Skin Penetration and Clinical Study", Skin Pharmacol., 1981, 1:246-249; Karger AG, Basel, Switzerland	
	R21	HOOIJBERG, E., et al., "NFAT-controlled expression of GFP permits visualization and isolation of antigen- stimulated primary human T cells," <i>Blood</i> , July 15, 2000, pp. 459-466, Vol. 96, No. 2.	
	R22	HORN, D., and RIEGER, J., "Organic Nanoparticles in the Aqueous Phase—Theory, Experiment, and Use", Angew. Che,. Int. Ed., 2001, 40:4330-4361; Wiley-VCH Verlag GmbH, Germany	
	R23	LEE, et al., Nature, 1981, pp. 228-232, Vol. 214.	
	R24	MCELWEE, K. J., et al., "Partial restoration of hair growth in the DEBR model for Alopecia areata after in vivo depletion of CD4+ T cells," <i>British Journal of Dermatology</i> , March 1999, pp. 432-437, Vol. 140, No. 3.	
·	R25	MEZEI M. and GULASEKHARAM V., "Liposomesa selective drug delivery system for the topical route of administration: Lotion dosage form.," <i>Life Sciences</i> , May 5, 1980, pp. 1473-1477, Vol. 26, No. 18.	
·	R26	MICHEL, et. al., "Effect of Liposomes on Percutaneous Penetration of Lipophilic Materials", International Journal of Pharmaceutics, 1992, pp. 93-105, Vol. 84.	

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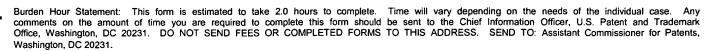
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A TO A CLASSIC FOR THE PARTIES IN THE Complete if Known Substitute for form 1449B/PTO **Application Number** 10/071,509 INFORMATION DISCLOSURE Filing Date February 8, 2002 STATEMENT BY APPLICANT **First Named Inventor** Alfred Fahr **Group Art Unit** 1614 (use as many sheets as necessary) **Examiner Name** unknown Sheet of 4 **Attorney Docket Number BPD-103**

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R27	NAEYAERT, J. M., et al., "Cyclosporin in atopic dermatitis: review of the literature and outline of a Belgian consensus," <i>Dermatology</i> , 1999, pp. 145-152, Vol. 198, No. 2.	
	R28	NICKOLOFF, B. J., GRIFFITHS, C. E., "Aberrant intercellular adhesion molecule-1 (ICAM-1) expression by hair-follicle epithelial cells and endothelial leukocyte adhesion molecule-1 (ELAM-1) by vascular cells are important adhesion-molecule alterations in alopecia areata," <i>J. Invest. Dermatol.</i> , May 1991, pp. 91S-92S, Vol. 96, No. 5.	
	R29	NIEMIEC, S.M., et al., "Influence of nonionic liposomal composition on topical delivery of peptide drugs into pilosebaceous units: an in vivo study using the hamster ear model," <i>Pharmaceutical Research</i> , August 1995, pp. 1184-1188, Vol. 12, No. 8.	
	R30	PERRET, C., et al., "Immunohistochemical analysis of T-cell subsets in the peribulbar and intrabulbar infiltrates of alopecia areata," Acta dermato-venereologica, 1984, pp. 26-30, Vol. 64, No. 1.	
	R31	SAFAVI, K. H., et al., "Incidence of alopecia areata in Olmsted County, Minnesota, 1975 through 1989," Mayo Clinic Proceedings, July 1995, pp. 628-633, Vol. 70, No. 7.	
,	R32	SUNDBERG, et al., Journal of Investigative Dermatology, 1995, pp. 32-33, Vol. 104.	
	R33	TOBIN, D. J., et al., "Autoantibodies to hair follicles in C3H/HeJ mice with alopecia areata-like hair loss," Journal of Investigative Dermatology, September 1997, pp. 329-333, Vol. 109, No. 3.	
	R34	VANLERBERGHE, et. al., "The effect of non-ionic surfactant vesicle (noisome) entrapment on the absorption and distribution of methotrexate in mice", J. Pharm. Pharmacol. (1985), 37:237-242	
	R35	WEINER, et. al., "Topical Delivery of Liposomally Encapsulated Interferon Evaluated in a Cutaneous Herpes Guinea Pig Model", Antimicrobial Agents and Chemotherapy, 1989, pp. 1217-1221, Vol. 33.	
"	R36	WEINER, N., et al., "Topical Application of Liposomally Entrapped Ciclosporin Evaluated by in vitro Diffusion Studies with Human Skin", Skin Pharmacol. 1991, 4:21-28	
	R37	WEINTRAUB, H. M., "Antisense RNA and DNA," Scientific American, January 1990, pp. 40-46, Vol. 262, No. 1.	
	R38		
	R39		

Examiner	Date	
Signature	Considered	

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.



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